

LISTING OF CLAIMS

The listing of claims will replace all prior versions, listings, of claims in the application.

Please amend claims 1, 2, 4, 5, 16, 17 and 21.

1. (Currently Amended) An orally administered agent free of a bioadhesive layer, comprising:

a drug-containing layer including a drug;

a first water-swellaable gel-forming layer provided on one side of the drug-containing layer either directly or via an intermediate layer, the first water-swellaable gel-forming layer not containing the drug;

a second water-swellaable gel-forming layer provided on the other side of the drug-containing layer either directly or via an intermediate layer, the second water-swellaable gel-forming layer not containing the drug, wherein

the first water-swellaable gel-forming layer and the second water-swellaable gel-forming layer contain a water-swellaable gel-forming agent and a film-forming agent that, together with the drug-containing layer, facilitate a digestive tract release of the drug, and

the content of the water-swellaable gel-forming agent in the first water-swellaable gel-forming layer or the second water-swellaable gel-forming layer is 15 to 70 wt%, and the content of the film-forming agent in the first water-swellaable gel-forming layer or the second water-swellaable gel-forming layer is 30 to 85 wt%.

2. (Currently Amended) The orally administered agent according to claim 1, wherein said orally administered agent is a film-shaped preparation formable into a plurality of configurations, such as flat or folded, wherein the film forming agent of the water-swellaable gel-forming layers is adjustable to modify a film strength of the water-swellaable gel-forming layers to correspond to a thickness of the drug-containing layer so that the film-shaped preparation gels when in contact with moisture to facilitate swallowing and releases the drug in the digestive tract without dissolving in the mouth.

3. (Canceled)

4. (Currently Amended) The orally administered agent according to claim 1, wherein said water-swellaable gel-forming agent is a ~~cross-linked carboxyvinyl polymer[[,]]~~ cross-linked by a polyvalent metal compound and said film-forming agent is polyvinyl alcohol.

5. (Currently Amended) The orally administered agent according to claim 4, wherein said ~~cross-linked carboxyvinyl polymer is a carboxyvinyl polymer cross-linked by a polyvalent metal compound~~ film-forming agent is polyvinyl alcohol.

6. (Canceled)

7. (Previously Presented) The orally administered agent according to claim 1, wherein the first water-swellaable gel-forming layer and the second water-swellaable gel forming layer are provided as outermost layers of said orally administered agent to form a mask for the taste and/or smell of a drug contained in said drug-containing layer.

8. (Previously Presented) The orally administered agent according to claim 1, wherein said drug-containing layer contains an edible polymer as a base.

9. (Original) The orally administered agent according to claim 8, wherein said edible polymer is cellulose and/or a cellulose derivative.

10. (Previously Presented) The orally administered agent according to claim 8, wherein the content of said edible polymer in said drug-containing layer is at least 20 wt%.

11. (Withdrawn) An orally administered agent/supporting substrate complex comprising the orally administered agent according to any one of claims 1 to 10, and a supporting substrate that supports the orally administered agent, wherein said orally administered agent is provided on said supporting substrate either directly or via an intermediate layer.

12. (Withdrawn) The orally administered agent/supporting substrate complex according to claim 11, wherein said supporting substrate has a gripping part and a mouth-inserting part, and said orally administered agent is provided on said mouth-inserting part.

13. (Canceled)

14. (Previously Presented) The orally administered agent of claim 1, wherein the drug-containing layer comprises one of a stomach-soluble polymer and an intestine-soluble polymer.

15. (Previously Presented) The orally administered agent of claim 14, wherein the one of the stomach-soluble polymer and the intestine-soluble polymer is cellulose and/or a cellulose derivative.

16. (Currently Amended) The orally administered agent of claim 1, wherein the water-swellaable gel-forming agent contained in the first water-swellaable gel-forming layer and the second water-swellaable gel-forming layer swells through moisture in saliva or other moisture in the mouth of a patient to form a gel that changes into a form having a size, shape, elasticity, and viscosity so that swallowing of the orally administered agent is easy for the patient and so that the drug-containing layer does not dissolve in the mouth.

17. (Currently Amended) An orally administered agent, having a structure comprising:
a plurality of drug containing layers~~[[:]]~~; and
water-swellaable gel-forming layers, wherein
the multiple drug-containing layers are heat-sealed via an intermediate layer which
includes a heat-sealing adhesive, and
the water-swellaable gel-forming layers are provided as ~~an~~ outermost layers of the orally
administered agent to cover the drug-containing layers.

18. (Previously Presented) The orally administered agent according to claim 17, wherein the heat-sealing adhesive is one of a homopolymer of vinyl acetate and a copolymer between vinyl acetate and vinyl pyrrolidone.

19. (Previously Presented) The orally administered agent according to claim 17, wherein the orally administered agent is free of a bioadhesive layer.

20. (Previously Presented) The orally administered agent according to claim 17, wherein a drug in the drug-containing layers is released in a stomach or an intestine.

21. (Currently Amended) The orally administered agent according to claim 17, wherein the orally administered agent is a film-shaped preparation formable into a plurality of configurations, such as flat or folded, wherein the film forming agent of the water-swellaable gel-forming layers is adjustable to modify a film strength of the water-swellaable gel-forming layers to correspond to a thickness of the drug-containing layer so that the film-shaped preparation gels when in contact with moisture to facilitate swallowing and releases the drug in the digestive tract without dissolving in the mouth.